

WHAT IS CLAIMED IS:

1. A device for accessing a mammalian duct and collecting cellular material from within the duct, said device comprising:

a catheter for being positioned within the duct, said catheter having a proximal end and a distal end, said distal end including an opening for delivering lavage fluid within the duct and receiving cellular material from within the duct;

a manifold hub in fluid communication with the catheter, said manifold hub comprising a distal end having a first port that is axially aligned with an internal lumen of the catheter, a second port positioned within the hub for infusing fluids into said hub and a third port positioned within the hub for collecting fluid from within the hub.

2. The device according to claim 1 wherein said manifold hub includes at least one sidewall that extends parallel to a longitudinal axis of the device, said at least one sidewall includes the infusion port and the collection port.

3. The device according to claim 2 wherein said infusion port and collection port are aligned with each other along the at least one sidewall of the hub.

4. The device according to claim 3 wherein the infusion port is positioned proximate the first port relative to said collection port.

5. The device according to claim 3 wherein the collection port is positioned between the infusion port and a proximal end of the hub.

6. The device according to claim 2 wherein said hub has a substantially circular cross section, and said infusion port and collection port are circumferentially spaced from each other around the hub.

7. The device according to claim 1 further including an infusion line connected to the infusion port and a collection line connected to the collection port.

8. The device according to claim 7 further including a fluid infusing member removably secured to a terminal end of the infusion line for delivering fluid to the infusion line and the hub.

9. The device according to claim 8 wherein said infusing member comprises a syringe.

10. The device according to claim 7 further including a collecting member removably secured to a terminal end of the collection line.

11. The device according to claim 10 wherein said collecting member comprises a syringe.

12. The device according to claim 1 wherein the distal opening of the catheter is capable of being moved between a closed position and an open position.

13. The device according to claim 12 further including a mechanism for moving the distal catheter opening between the open and closed positions.

14. The device according to claim 13 wherein said mechanism includes a wire extending between the proximal and distal ends of the catheter.

15. The device according to claim 12 wherein said distal end of the catheter is formed of a shape memory material that opens in response to the application of a stimulus.

16. The device according to claim 15 wherein said stimulus includes heat or electric current.

17. The device according to claim 15 wherein said shape memory material is Nitinol.

18. The device according to claim 12 wherein the distal end has a larger opening than the proximal end of the catheter when the distal end is in the open position.

19. The device according to claim 1 further including a guide member for introducing the catheter into the duct.

20. The device according to claim 19 wherein the guide member includes a dilator having a tapered distal end.

21. The device according to claim 20 wherein the distal end of the dilator includes at least one opening for receiving a medicament.

22. The device according to claim 21 wherein the medicament is lidocaine.

23. The device according to claim 1 wherein the distal end of the manifold hub is removably secured within the catheter.

24. The device according to claim 23 wherein the distal end of the manifold hub forms a luer lock connection with the catheter.

25. A ductal access device comprising a first elongated member for positioning within a breast duct, said first member comprising an internal lumen, and a manifold hub removably secured to said first member and being in fluid communication with a proximal end of the first elongated member.

26. The device according to claim 25 wherein said manifold hub includes a first opening that is axially aligned with the internal lumen of the elongated member.

27. The device according to claim 26 wherein said first opening is located at a distal end of the hub that is secured to said elongated member.

28. The device according to claim 27 wherein said manifold hub includes a sidewall carrying an infusion port and a collection port, said infusion port being positioned between the collection port and the first opening.

28. The device according to claim 26 wherein said first opening is positioned at a proximal end of the manifold hub, and a sidewall of the manifold hub extends between the first opening and a distal end of the manifold hub.

29. The device according to claim 28 wherein the distal end of the hub includes an opening in fluid communication with the inner lumen of the catheter, said sidewall includes a

fluid infusion port for delivering fluid to the hub, and the first opening forms a collection port for collecting fluid from said manifold hub.

30. The device according to claim 28 wherein the distal end of the hub includes an opening in fluid communication with the inner lumen of the catheter, said sidewall includes a fluid collection port for receiving fluid from within the hub, and the first opening forms a fluid infusion port for delivering fluid to the hub.

31. The device according to claim 25 wherein the elongated member comprises a catheter having a distal end that can move between an open position and a closed position.

32. The device according to claim 31 wherein the distal end of the catheter has a first inner diameter when the end is in a closed position and a second, larger inner diameter when the end is in the open position.

33. The device according to claim 32 further comprising a mechanism for moving the distal end between the open and closed positions.

34. A ductal access device for accessing a breast duct and collecting cellular material from within the duct, said device comprising:

an elongated member comprising a proximal end, a distal end and a lumen extending between the proximal and distal ends;

a hub for being removably secured to said elongated member, said hub comprising an infusion port for delivering fluid to the catheter lumen, said infusion port being in fluid communication with an infusion device, and a collection port for receiving fluid and cellular material within the hub.

35. The device according to claim 34 wherein the lumen is open to the hub.

36. The device according to claim 35 wherein said collection port is in fluid communication with a fluid collection device.

37. The device according to claim 36 wherein the fluid collection device includes a source for creating negative pressure within the hub and a fluid collection line extending between said fluid collection port and the fluid collection device.

38. The device according to claim 35 further including a tubular member extending between said infusion port and the infusion device for delivering fluid from said infusion device to the hub.

39. The device according to claim 35 wherein the hub includes a distal end that is removably positioned within the proximal end of the elongated member.

40. A ductal access device for accessing a breast duct and collecting cellular material from within the duct, said device comprising a first elongated member having a first outer diameter sized for positioning within the breast duct and a second elongated member having a second outer diameter that is greater than said first outer diameter for preventing said second elongated member from entering the breast duct.

41. The device according to claim 40 wherein the first elongated member comprises a catheter having an internal lumen for introducing fluids into the breast duct and receiving fluid from within the breast duct.

42. The device according to claim 41 wherein said second elongated member comprises a hub including a lower port at a distal end for forming a fluid path with the internal lumen of the catheter.

43. The device according to claim 42 wherein the hub further includes first and second side ports spaced above the lower port.

44. The device according to claim 43 wherein the first and second side ports are at the same height along a sidewall of the hub relative to the lower port.

45. The device according to claim 42 wherein the first and second side ports are at different heights along a sidewall of the hub relative to the lower port.

46. The device according to claim 41 wherein the catheter has an outer diameter of about 0.50 inch or less.

47. The device according to claim 46 wherein the outer diameter is in the range from about 0.010 inch to 0.050 inch.

48. The device according to claim 41 wherein the diameter of the inner lumen is about 0.007 inch or greater.

49. The device according to claim 42 further comprising an infusion tube connected to the first port of the hub; and a collection tube connected to the second port of the hub.

50. The device according to claim 42 wherein the manifold has a volume in the range from about 0.01 cc to 1.0 cc.

51. A ductal access device for accessing a breast duct and collecting cellular material from within the duct, said device comprising a first elongated member having a proximal end, a distal end and an internal lumen extending between said ends; a manifold hub having a proximal end and a distal end, said manifold hub having a lower opening for being in fluid communication with said inner lumen; and an elongated guide member for extending through at least one of the first elongated member and the hub for positioning a portion of the first elongated member in the breast duct.

52. The device according to claim 51 wherein the first elongated member comprises a catheter having a well at its proximal end.

53. The device according to claim 52 wherein said hub includes a distal end that is removably secured within said well after the catheter is positioned in the breast duct and the guide member has been removed from the internal lumen.

53. The device according to claim 53 wherein the distal end of the hub forms a luer lock fit with the well of the catheter.

54. The device according to claim 51 wherein the guide member includes a distal end having a plurality of openings.

55. The device according to claim 54 wherein said openings carry a medicament for administering to the lining of the breast duct.

56. A ductal access device for accessing a breast duct and collecting cellular material from within the duct, said device comprising a first elongated member having a distal end that can move between an open position and a closed position, a proximal end and an internal lumen extending between said ends and a manifold hub having a proximal end and a distal end, said manifold hub having a lower opening for being in fluid communication with said inner lumen.

57. The device according to claim 56 wherein the distal end of the elongated member has a first inner diameter when in the closed position and a second, larger diameter when in the open position.

58. The device according to claim 56 wherein said elongated member comprises a catheter, and further including a mechanism for moving the distal catheter opening between the open and closed positions.

59. The device according to claim 58 wherein said mechanism includes a wire extending between the proximal and distal ends of the catheter.

60. The device according to claim 57 wherein said distal end of the catheter is formed of a shape memory material that opens in response to the application of a stimulus.

61. The device according to claim 60 wherein said stimulus includes heat or electric current.

62. The device according to claim 60 wherein said shape memory material is Nitinol.

63. A method for lavaging a ductal network in a human breast, said method comprising the steps of:

inserting a distal end of a catheter having an internal lumen through a ductal orifice and into a distal lumen of the ductal network;

infusing a lavage fluid into a manifold hub through an infusion port;

introducing the lavage fluid into the ductal network;

withdrawing the lavage fluid and substances borne by the lavage fluid from the ductal network; and

delivering the withdrawn fluid and substances to a collection device through a collection port in the hub.

64. The method according to claim 63 where said step of infusing lavage fluid into the hub includes delivering the lavage fluid from an infusion device to the infusion port via an infusion tube.

65. The method according to claim 63 wherein the step of withdrawing the lavage fluid and substances includes the step of applying a negative pressure within the hub.

66. The method according to claim 65 wherein the negative pressure is applied by the collection device.

67. The method according to claim 65 wherein the method further includes the step of externally massaging the breast so that the fluid and substances are forced in the direction of the hub.

68. The method according to claim 63 wherein the step of delivering the fluid and substances to the collection device includes infusing fluid into the hub.

69. The method according to claim 63 wherein the step of introducing the lavage fluid into the ductal network includes the step of applying a positive fluid infusion pressure within the hub.

70. A method for obtaining cellular material from a mammalian breast duct network, said method comprising the steps of:

- inserting a distal end of an elongated device having an internal lumen through a ductal orifice and into a distal lumen of the ductal network;
- infusing a lavage fluid into a manifold hub through an infusion port;
- introducing the lavage fluid into the ductal network through the lumen;
- massaging an area of the breast; and
- delivering the lavage fluid and substances borne by the lavage fluid from the ductal network to a collection device through a collection port in the hub.

71. The method according to claim 70 further including the step of retaining at least 2 mils of the lavage fluid within the breast duct for a predetermined period of time.

72. The method according to claim 71 wherein the predetermined period of time is less than one second.

73. The method according to claim 71 wherein the predetermined period of time is between about one second and one hour.

74. The method according to claim 70 further including the step of creating a negative pressure in at least a portion of the hub.

75. The method according to claim 74 wherein the negative pressure is created by the collection device.

76. The method according to claim 70 wherein a collection tube extends between the collection port and the collection device

77. The method according to claim 70 wherein the step of delivering the fluid and substances to the collection device includes infusing fluid into the hub.

78. The method according to claim 70 wherein the step of introducing the lavage fluid into the ductal network includes the step of applying a positive fluid infusion pressure within the hub.